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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/088,025 03/14/2002 Andreas Reindl 3557-12 4942 02/10/2005 EXAMINER 7590 Nixon & Vanderhye KALLIS, RUSSELL 8th Floor ART UNIT PAPER NUMBER 1100 North Glebe Road Arlington, VA 22201-4714 1638

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/088,025	REINDL ET AL.
	Examiner	Art Unit
	Russell Kallis	1638
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on 29 October 2004 and 17 November 2004.		
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
<ul> <li>4)  Claim(s) 1-18 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-18 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>		
Application Papers		
9)⊠ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>14 March 2002</u> is/are: a) $\square$ accepted or b) $\boxtimes$ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date 3/14/02.</li> </ul>	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: <u>attachements</u>	atent Application (PTO-152)

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-16 in the reply filed on 10/29/2004 is acknowledged. The traversal is on the ground(s) that no serious burden has been established. This is not found persuasive because searching the extra group would constitute a serious burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim 17 is amended and Claim 18 newly added. Claims 1-18 are pending and examined.

#### Claim Objections

Claim 1 is objected to because of the following informalities: In line 2 "translator" should be --translocator--. Appropriate correction is required.

## Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: The specification should identify the sequences in figures 1 and 2 using sequence identifiers or the drawings should be amended to show the sequence identifiers.

- § 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;
- (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The added claimed material which is not supported by the original disclosure is as follows: Amended Claim 6 recites the amino acid sequence of SEQ ID NO: 1, while the specification only supports the polynucleotide sequence of SEQ ID NO: 1. Thus, the claims are drawn to NEW MATTER. Applicant is invited to point to the page and line number in the specification where support can be found. Absent of such support, Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, in lines 3 and 4, "is modified" and "said modification" do not point to the same thing and thus it is not clear what is modified. Further, "is modified" is closed language and "said modification comprises" is open language, and thus the modified regulatory sequence or gene copy number of an ATP/ADP translocator gene do not comprise the modification to the amino acids.

Claim 1 recites the limitation "said modification" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

In Claim 6, line 2, it is unclear which version of GenBank or EMBL Accession Number Z49227 is being referenced because GenBank Accession numbers can be updated at any time. For example, GenBank Accession No. Z49227 has changed since publication. See attached NCBI printouts #1 and #2 in attachment. In addition, SEQ ID NO: 1 is a nucleic acid sequence.

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13 and 16-26 of

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copending Application No. 09/674,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of co-pending U.S. application 09/674,768 are drawn to plants, plant cells and seeds transformed with a nucleic acid encoding a plastidial ATP/ADP translocator (e.g. the AATP1 gene from *Arabidopsis*, SEQ ID NO: 5) and methods comprising transforming a plant cell or plant by integrating a foreing nucleic acid molecule encoding a plastidial ATP/ADP translocator and thus render Claims 1-18 drawn to an ATP/ADP translocator gene (e.g. the AATP1 gene from *Arabidopsis*, SEQ ID NO: 1) of the instant application obvious.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 13 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed plants and seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claims 1-7, 13 and 17 are drawn to progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three fourths of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants

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and seeds that would occur in nature. See American Wood v. Fiber Distintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980).

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tjaden J. et al. The Plant Journal, 1998, Vol. 16, No. 5; pp. 531-540.

Tjaden teaches potato plants transformed with a construct comprising the 35S sequence, the heterologous AATP1 plastidic ATP/ADP translocator gene from *Arabidopsis* that comprises SEQ ID NO: 1 (Z49227) in sense and antisense orientation, wherein the AATP1 antisense construct downregulated ATP/ADP translocator activity thus decreasing ATP import in transformed potato and AATP1 sense transformed potato plants demonstrated an upregulated ATP/ADP translocator activity and increased ATP import (see page 531 column 2, lines 16-20; page 532 column 2 to page 533 column 2; and see also Table 2 page 533); and wherein modified amounts of one or more amino acids is an inherent feature of a plant transformed with an ATP/ADP translocator gene, and thus the reference teaches all the limitations of Claims 1-18.

All Claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kally

Russell Kallis Ph.D. January 28, 2005